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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,460	03/11/2005	Josef Beden	P70415US0	2533

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,460	BEDEN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 May 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, 8, 9, 12, 14, 15, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg.

In the specification and figures, Twardowski discloses the method substantially as claimed by applicant. With regard to claims 1, 8, 9, and 17, Twardowski discloses a method for return of blood from a treatment apparatus. The apparatus comprises a dialyzer 100, two lines 144, 146, with outlets 145a, 145b, blood pump 148, first valve 168 in the first line, second valve 174 in the second line line/port 166 for feeding of substituate fluid 164 in a predilution location. Twardowski discloses that after the completion of blood treatment, first valve 168 is opened to connect saline bag exclusively to the blood line, indicating that valve 174 is closed. Saline moves into inlet line 144, pushing blood out of the systemback to the patient. Then valve 168 closes and saline is pushed, with use of pump 148, through the outlet line 146, returning blood to the patient (see column 14, lines 39-60).

Twardowski fails to disclose the presence and use of a substituate pump to move the substituate fluid through the circuit. Polaschegg discloses and illustrates a dialysis

apparatus with a substitute fluid in chamber 88 connected via line 102 and pump 84 to blood inlet path 36. The pump is used to move fluid through the blood path in order to provide predilution and rinseback after the completion of the procedure (see column 8, lines 13-40).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add and use the substituate pump disclosed by Polaschegg to the apparatus and method disclosed by Twardowski in order to more accurately control the movement of substituate fluid through the circuit, as suggested by Polaschegg.

With regard to claim 2, Polaschegg discloses that substituate fluid may be administered to the patient in a postdilution location during a rinseback operation (see column 8, lines 13-40), suggesting the postdilution rinseback operation claimed by applicant.

With regard to claims 4-5, Polaschegg specifically discloses that the apparatus may be used for hemodiafiltration (see column 1, lines 17-24).

With regard to claims 12 and 20, Polaschegg illustrates that predilution line 102 opens into blood line 36 downstream of blood pump 42 and upstream of blood treatment element 12.

With regard to claim 14, the first and second line disclosed by Twardowski are used as conduits for blood transport during blood treatment and allow for return of displaced blood (see FIG 1).

With regard to claim 15, the first and second line disclosed by Twardowski are used as conduits for blood transport during blood treatment and allow for return of displaced blood (see FIG 1).

With regard to claim 20, Polaschegg illustrates that predilution port 102 is located downstream of blood pump 42.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg , further in view of US 5,470,483 to Bene et al.

In the specification and figures, Twardowski and Polaschegg suggest the method substantially as claimed by applicant (see rejection above) with the exception of the postdilution line located downstream of the blood treatment element and upstream of the second valve. Bene discloses an extracorporeal blood treatment system with a posdilution line that connects to a blood return line downstream of treatment element 4 and upstream of valve 18 in order to create a recirculation loop for blood treatment (see column 4, lines 33-45). Therefore, it would have been obvious to locate the postdilution line in the method suggested by the prior art downstream of the blood treatment element and upstream of a valve element in order to create a recirculation loop, as taught by Bene.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 4,770,769 to Schael.

In the specification and figures, the prior art suggest the apparatus and method substantially as claimed by applicant (see rejection above) with the exception of a membrane pump as the substituate pump. Schael discloses a hemodialysis apparatus that uses membrane pumps in the device in order to accurately control the operation of the system in response to system and patient parameters (see column 6, line 50 to column 7, line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute a membrane pump as disclosed by Schael for the pumps in the system suggested by Twardowski and Polaschegg in order to provide accurate pumping control, as taught by Schael.

5. Claims 6, 7, 10, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 5,783,072 to Kenley et al.

In the specification and figures, the prior art suggest the apparatus and method substantially as claimed by applicant (see rejection above) with the exception of using optical sensors to detect the presence of substituate fluid rather than blood in the tubing lines. Kenley discloses a method and apparatus for blood filtration that uses optical sensors 446, 486 in arterial and venous lines 432, 492 to sense the concentration of blood in the lines. When the concentration has reached a certain level, indicating that

the substituate fluid is flowing through the lines, the rinseback is stopped to prevent excess fluid return to the patient (see column 48, lines 17-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add optical sensors as disclosed by Kenley to the apparatus and method suggested by the prior art in order to monitor fluid return and prevent excess fluid from returning to the patient, as taught by Kenley.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 3,898,017 to Mandroian.

In the specification and figures, the prior art suggest the apparatus and method substantially as claimed by applicant (see rejection above) with the exception of the pumps being configured as double pumps arranged in parallel. Mandroian discloses a pumping system that may be used to pump sensitive fluids such as blood (see column 1, lines 15-25). The pumps comprise membranes between an air chamber that expands and contracts to move the motive fluid through the pumping chambers. Mandroian specifically discloses that the pump may be arranged to comprise two pumps connected in parallel in order to provide a continuous discharge flow (see column 6, lines 35-44). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to replace the pumps in the method suggested by the prior art with the membrane double pumps connected in parallel as disclosed by Mandroian in order to provide continuous discharge flow, as taught by Mandroian.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 4,770,769 to Schael.

In the specification and figures, Twardowski and Polaschegg suggest the method substantially as claimed by applicant. (see rejection above) with the exception of a membrane pump as the substituate pump. Schael discloses a hemodialysis apparatus that uses membrane pumps in the device in order to accurately control the operation of the system in response to system and patient parameters (see column 6, line 50 to column 7, line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute a membrane pump as disclosed by Schael for the pumps in the system suggested by Twardowski and Polaschegg in order to provide accurate pumping control, as taught by Schael.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 5,783,072 to Kenley et al.

In the specification and figures, the prior art suggests the apparatus and method substantially as claimed by applicant (see rejection above) with the exception of using optical sensors to detect the presence of substituate fluid rather than blood in the tubing lines. Kenley discloses a method and apparatus for blood filtration that uses optical sensors 446, 486 in arterial and venous lines 432, 492 to sense the concentration of blood in the lines. When the concentration has reached a certain level, indicating that

the substituate fluid is flowing through the lines, the rinseback is stopped to prevent excess fluid return to the patient (see column 48, lines 17-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add optical sensors as disclosed by Kenley to the apparatus and method suggested by the prior art in order to monitor fluid return and prevent excess fluid from returning to the patient, as taught by Kenley.

Response to Arguments

9. Applicant's arguments filed 13 November 2007 have been entered and fully considered, but they are not persuasive.

10. Applicant argues that the combination of Twardowski and Polaschegg is not suitable for hemofiltration treatment or hemodiafiltration treatment. However, the Examiner notes that that the features upon which applicant relies (i.e., hemofiltration or hemodiafiltration treatment) are not recited in the claims rejected over the combination of Twardowski and Polaschegg. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the Twardowski and Polaschegg references suggest the method claimed by applicant.

11. Applicant further argues that the sequence of pumping steps suggested by the prior art is different than the claimed sequence of steps. However, it has been held that it is improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on

the performance of the method steps, and the specification did not directly or implicitly require a particular order. See MPEP 2111.01(II). In the instant case, the method claimed by applicant does not recite a specific sequential order to the steps. The method suggested by the prior art and the method claimed by applicant appear to perform the same function, regardless of the order of the steps used in the method. Accordingly, it is the position of the Examiner that the method suggested by the prior art renders the instantly claimed method unpatentable.

12. Applicant notes that the predilution line claimed by applicant opens into the blood supply line downstream of the blood pump. Polaschegg discloses the same arrangement, with predilution line 102 opening into blood line 36 downstream of pump 46 and upstream of blood treatment element 12 (see FIG 2).

13. Applicant's arguments with respect to the rejections over Twardowski and Bene have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
14 January 2008